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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,748	05/29/2001	Brett P Monia	RTSP-0100	1204

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EXAMINER

SCHULTZ, JAMES

ART UNIT PAPER NUMBER

1635

DATE MAILED: 04/02/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/763,748

Applicant(s)

MONIA ET AL.

Examiner

J. Douglas Schultz

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2 and 5-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

Application/Control Number: 09/763,748

Page 2

Art Unit: 1635

### DETAILED ACTION

Applicant's response filed January 27, 2003 has been considered. Rejections and/or objections not reiterated from the previous office action mailed August 27, 2002 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

#### *Response to Arguments*

Claims 1, 2, and 5-8 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Goeddel et al. (U.S. Patent Number 5,563,039, applicants IDS) in view of Froehler, BC (U.S. Patent Number 5,256,775), both of record, for the same reasons as set forth in the Office action mailed August 27, 2002.

Applicants have traversed the rejection above on the grounds that while Goeddel et al. generally teach antisense inhibition of TRADD, that nowhere does Goeddel teach the use of antisense compounds 8 to 30 nucleotides in length, nor does it teach antisense targeted to SEQ ID NO:1 as identified in the present application, and therefore does not teach all the limitations of the claims. Applicant also argues that the patent of Froehler does not teach antisense targeted to SEQ ID NO:1.

These arguments are not considered convincing. As indicated in the previous Office action, one would have been motivated to make such compounds because Goeddel et al. expressly teach antisense inhibition of the TRADD mRNA transcript that is, contrary to applicants' contention, identical to applicants' claimed TRADD target of SEQ ID NO: 1 (see

attached sequence alignment). Goeddel thus expressly states that one of ordinary skill in the art would have been motivated to make antisense molecules targeted to the instant TRADD target of SEQ ID NO: 1. Froehler teaches the synthesis and use of antisense oligos that are between 8 and 30 nucleotides long to inhibit transcripts of known sequence, and further teaches how to modify such oligos in the manner claimed by applicant. As stated in the previous Office action, since Froehler teaches that such modifications confer nuclease resistance which prolongs their bioactivity, one would have been motivated make oligonucleotides that incorporate such modifications. Finally, because the steps involved in such modifications are taught by Froehler and are routine to one of ordinary skill in the art, this combination also provides a reasonable expectation of success which render the invention of the claims above obvious under 35 U.S.C. § 103(a).

Applicant also argues that neither Goeddel et al. nor Froehler, when viewed individually, teach antisense oligos 8 to 30 nucleotides long that target and inhibit the expression to SEQ ID NO:1, TRADD. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). It is acknowledged that the references when viewed individually do not teach the presently claimed invention; however, the test for obviousness is what the combined teaching of the prior art would have suggested to those of ordinary skill in the art. Goeddel et al. expressly teach antisense inhibition of applicants instant TRADD mRNA transcript. Froehler teaches making and using oligonucleotides between

Art Unit: 1635

8 and 30 nucleotides long that comprise applicants' modifications in a method of inhibiting a target transcript. Thus, all the elements of applicants' claims are taught by the prior art, as is express motivation, and an expectation of success. Accordingly the invention of the above claims is considered obvious under 35 U.S.C. § 103(a).

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1635

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355.

The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD  
March 28, 2003



JOHN L. LEGUYADER  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600